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10/696,258

10/28/2003

Rebecca Gomez

REB/001 Div

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02/22/2010

KRAMER LEVIN NAFTALIS & FRANKEL LLP
INTELLECTUAL PROPERTY DEPARTMENT
1177 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER

SHAY, DAVID M

ART UNIT

PAPER NUMBER

3769

NOTIFICATION DATE

DELIVERY MODE

02/22/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

klpatent@kramerlevin.com

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/696,258 | Applicant(s) GOMEZ, REBECCA | |
| | Examiner david shay | Art Unit 3769 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on November 12, 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-15, 19, 21, 27, 33-36 and 38-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-15, 19, 21, 27, 33-36 and 38-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Several Declarations have been submitted by applicant. The examiner will now analyze these Declarations.

A Declaration submitted by Maria Suarez, states at paragraph 1 that Declarant was a patient suffering from grade 4 hemorrhoids that had become thrombosed. At paragraph 2, Declarant notes that she had tried various treatments, including suppositories and various topical agents including Preparation H and Peranex, to little or no effect. At paragraph 3, Declarant states that her doctor had tried draining the hemorrhoid, but felt that surgery was inevitable. In paragraph 4 Declarant states that she has reviewed the instant application and the claims thereof. At paragraph 5, Declarant states that she suffered from the hemorrhoids for 13 days prior to using the claimed invention. At paragraph 6, Declarant states that after suffering from the previously discussed hemorrhoid, Declarant used the claimed invention in the hopes of avoiding surgery. At paragraph 7, Declarant notes that the claimed device was worn continuously, but allowed free movement without pulling of the skin or any other discomfort. Declarant also notes that she was able to perform her normal daily activities without encumbrance while using the device, including going out in public, as the device did not show through clothing. In paragraph 8, Declarant notes that she was able to return to work immediately, and was able to concentrate and perform well at work due to using the device. Declarant then states, in paragraph 9, that “this was one of the most severe hemorrhoids I had experienced” and noted that the claimed invention allowed her to heal very rapidly and avoid surgery. Declarant’s statements are noted, as to the efficacy and convenience of the device.

A second declaration by Sandra L. Curet was also submitted. The examiner will now review this Declaration. Declarant begins by noting her qualifications: she graduated as an MD

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from The University of Puerto Rico, School of Medicine and practiced for the last 17 years as an Obstetric and Gynecological physician, a position that enabled her to become very familiar with the ailment of hemorrhoids. In paragraph 3, Declarant avers familiarity with the claimed invention and having reviewed the application and claims. In paragraph 4, Declarant asserts that she is very familiar with the “design and purpose” of the claimed invention, stating the claimed invention “has an ergonomic structure which does not restrict a patient’s movement and is comfortable to wear, thus allowing the patient to continue their daily activities despite the presence of the hemorrhoid or the wearing of the claimed invention”. Declarant goes on to state that the claimed invention operates by separating the inflamed tissue, resulting in quickened healing and reduction of the pain associated with the hemorrhoid and that the invention is easily applied and is user friendly for the patient. At paragraph 5, Declarant states that in her expert opinion, the product (presumably the claimed invention) is very effective in providing pain relief and allowing healing, and that she is eager for the claimed invention to become available commercially, so she may recommend it’s usage to her patients. At paragraph 6, Declarant asserts a familiarity with the reference to Rosenberg applied to the claims. At paragraph 7 Declarant states that she has compared the technology described in the claimed invention to that of Rosenberg, noting that Rosenberg describes a “reverse bandaging” technique wherein adhesive strapping is applied to the buttocks and crossed in front of the abdomen. At paragraph 8, Declarant asserts that “the purpose and technology in Rosenberg are different from the claimed invention”, stating that “Rosenberg is designed to work in a different anatomical area than the claimed invention” and that Rosenberg is designed for treating the wound resulting from the removal of a pilonidal cyst, while the instant invention can be used for reducing

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inflammation and pain associated with a hemorrhoid. At paragraph 9, Declarant states that “the stated differences between the invention and the prior art “demonstrate the superiority of the claimed invention over Rosenberg”. At paragraph 10, Declarant states that in her opinion, the superiority of the instant device, and the differences between the instant device and the prior art would not have been obvious to one of ordinary skill in the art. At paragraph 11, Declarant states that with regard to the device of Rosenberg and the instant device, that she finds “no similarities in the purpose, application, and design” of the two devices.

The examiner notes the statements made by Declarant in paragraphs 1-7. Subsequent statements, however, require closer scrutiny. The statement that “the purpose and technology in Rosenberg are different from the claimed invention”, is somewhat puzzling. It is quite clear from the Rosenberg publication that “all factors causing friction in daily work habits prevented epithelialization” (see Rosenberg, page 290, column 1, second paragraph, third sentence) thus clearly Rosenberg identified friction as an impediment to the proper healing of the wound. Rosenberg also identified the solution to this problem – separation of the gluteal cleft (see Rosenberg, page 290, the paragraph beginning at column 2, second sentence). When faced with recalcitrant cases, which were determined to be resistant to treatment due only to “mechanical factors” (see the sentence bridging pages 290 and 291 of Rosenberg), Rosenberg determined to use adhesive strapping “on either side of the wound” wherein the “net effect was to flatten out the wound and remove most of the angle of the intergluteal clefts” (see page 291, column 1, first full paragraph). Clearly Rosenberg understood that the frictional engagement of the buttocks with the injured tissue was a barrier to proper healing, and that the solution was to tape the buttocks out of the way. Further, while Declarant’s statement that “Rosenberg is designed to

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work in a different anatomical area than the claimed invention” may be true, it is also true that the “different anatomical area” is only inches from the area treated by applicant, and that the area still involves the buttocks. Similarly, the manner in which the “superiority” of the instant device over Rosenberg manifests itself is not clear, as it appears no comparative testing was done to determine the relative efficaciousness of the two devices. Thus while the assertion of superiority in paragraph 9 is noted, it remains only an assertion. Declarant’s opinion that the differences between the two devices would not be obvious, asserted in paragraph 10 are also noted.

However, the legal test for obviousness is not whether the differences between two devices are obvious, but rather whether one of ordinary skill in the art would find it obvious to modify the prior art device to produce the claimed device, given the teachings of the prior art and the knowledge and level of skill of one of ordinary skill in the art. Thus while Declarant may find “no similarities in the purpose, application, and design” of the two devices, the examiner has found many: both devices seek to prevent mechanical friction on tissue which is healing; both devices do so by allowing the buttocks to be held separated, so as to minimize such friction; both devices effect this separation by employing adhesive elements that maintain the buttocks in a separated condition, while allowing the wearer to proceed with normal activities.

A third declaration by Randolph M. Steinhagen was also submitted. The examiner will now review this Declaration. Declarant begins by noting his qualifications: he is the Chief of the Division of Colon and Rectal surgery at Mount Sinai Medical Center and is the Professor of Surgery in the Mount Sinai School of Medicine. In paragraph 2, Declarant avers familiarity with the claimed invention and having reviewed the application and claims. In paragraph 3, Declarant asserts that he worked in a clinical trial of the claimed invention, the results of which indicated

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that the claimed invention “was generally a success and preferred by the subjects of the trial”. At paragraph 4, Declarant asserts a familiarity with the reference to Rosenberg applied to the claims. At paragraph 5 Declarant states that he has compared the technology described in the claimed invention to that of Rosenberg, noting that Rosenberg describes a “strapping” technique wherein adhesive strapping is applied to the buttocks and crossed in front of the abdomen. At paragraph 6, Declarant asserts that the device of Rosenberg is applied to a different part of the body than the claimed invention and is for a different purpose, noting that the claimed invention “includes a unique shape and structure that is designed to reduce inflammation in the anal area and can provide relief of symptomatic hemorrhoids”, further noting that this obviates the need for surgery. At paragraph 7, Declarant states that “the claimed invention has a unique shape and structure not shown by Rosenberg” and continuing, states that the invention “can operate to reduce inflammation by lifting the inflamed tissue at a very specific angle that follows the anatomy of the patient’s body”. Declarant also asserts that this “particular lifting that is provided by the unique shape and structure of the claimed invention can allow the hemorrhoid to return to its normal position, thereby resulting in enhanced healing effects of the inflamed tissue” and continues, stating that “the specific angle at which the claimed invention lifts the inflamed tissue and does not hinder movement of a patient’s body” which allows “a patient to walk, sit sleep, or otherwise continue their daily life without discomfort, despite the presence of the hemorrhoids condition or the application of the claimed invention. Concluding, Declarant asserts “Rosenberg does not describe such a unique shape and structure and therefore does not produce the above-mentioned benefits of the claimed invention”. At paragraph 8, Declarant stated differences between the invention and the prior art “demonstrate the superiority of the claimed invention

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over Rosenberg”. At paragraph 9, Declarant states that in his opinion, the superiority of the instant device, and the differences between the instant device and the prior art would not have been obvious to one of ordinary skill in the art at the time the application was filed. At paragraph 10, Declarant states that in his expert opinion many people could benefit from the claimed invention, which provides the benefits such as enhanced healing and mitigating the need for surgery. At paragraph 11, Declarant that Rosenberg does not show the claimed invention, nor to Declarant’s knowledge, is any produce similar to the claimed invention currently commercially available and after comparing the device of Rosenberg with the instant device, that he concludes “that any supposed similarities between Rosenberg and the claimed invention are minimal at best and negligible”.

The examiner notes the statements made by Declarant in paragraphs 1-5 and 10. Subsequent statements, however, require closer scrutiny. Declarant’s statement in paragraph 6, that the device of Rosenberg is applied to a different part of the body than the claimed invention and is for a different purpose, noting that the claimed invention “includes a unique shape and structure that is designed to reduce inflammation in the anal area and can provide relief of symptomatic hemorrhoids” may be true, it is also true that the “different part of the body” is only inches from the body part treated by applicant, and that the area still involves the buttocks. Further, it seems apparent that the device of Rosenberg, applied a few inches farther down the buttocks, would have the same effect as the device of applicant. The statement in paragraph 7 that “the claimed invention has a unique shape and structure not shown by Rosenberg” is noted, however, it is not clear, that the device of Rosenberg, properly applied by one of ordinary skill in the art of hemorrhoid treatment would not produce the same results, and thus would be able to

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“operate to reduce inflammation by lifting the inflamed tissue at a very specific angle that follows the anatomy of the patient’s body” and produce the “particular lifting” since this could be produced by separating the gluteal cleft so as to reduce or prevent mechanical friction (as taught to be desirable by Rosenberg, as set forth above) on the hemorrhoid. This would (via the shrinkage of the tissue due to the removal of the irritation caused by the friction from the buttocks during normal motion) “allow the hemorrhoid to return to its normal position, thereby resulting in enhanced healing effects of the inflamed tissue”. Further, there is no evidence that the device of Rosenberg “does not hinder movement of a patient’s body” which allows “a patient to walk, sit sleep, or otherwise continue their daily life without discomfort, despite the presence of the hemorrhoids condition or the application” thereof. Indeed, the configuration of the device of Rosenberg is similar to a belt, which is well known in the art to allow a wearer to perform daily activities normally and in comfort. As to Declarant’s concluding assertion, which states that “Rosenberg does not describe such a unique shape and structure and therefore does not produce the above-mentioned benefits of the claimed invention”, the examiner finds no correlation between the premise and the conclusion since, for example, a regular piece of tape, such as used by Rosenberg, could be affixed to the patient in a curvilinear manner (albeit with some portions of the tape not contacting the skin on the inner portion of the curve) and perform in the same way. Thus, the manner in which the “superiority” of the instant device over Rosenberg manifests itself is not clear, as it appears no comparative testing was done to determine the relative efficaciousness of the two devices. Thus while the assertion of superiority in paragraph 8 is noted, it remains only an assertion. Declarant’s opinion that the differences between the two devices would not be obvious, asserted in paragraph 9 are also noted. However,

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the legal test for obviousness is not whether the differences between two devices are obvious, but rather whether one of ordinary skill in the art would find it obvious to modify the prior art device to produce the claimed device, given the teachings of the prior art and the knowledge and level of skill of one of ordinary skill in the art. Thus while Declarant may find that “Rosenberg does not show the claimed invention”, the examiner notes that both devices seek to prevent mechanical friction on tissue which is healing; both devices do so by allowing the buttocks to be held separated, so as to minimize such friction; both devices effect this separation by employing adhesive elements that maintain the buttocks in a separated condition, while allowing the wearer to proceed with normal activities, the absence of similar products in the marketplace does not speak to the matter of non-obviousness, as this may be due to other factors, such as the ability of available surgical tape to perform the same function.

A fourth declaration by Jeffrey Stephen Freed was also submitted. The examiner will now review this Declaration. Declarant begins by noting his qualifications: he graduated cum laude from the State University of New York School of Medicine, he currently specializes in proctology and in general surgery, and has been an associate attending at Mount Sinai Medical Center since 1992; Section Chief of Surgery at Bronx Veterans Hospital since 1979; attending at Beth Israel Hospital since 1982; attending at Lenox Hill Hospital since 1987; and is the Chief of the Division of Colon and Rectal surgery at Mount Sinai Medical Center and has been an associate clinical professor at Mount Sinai Medical Center since 1992. In paragraph 4, Declarant avers familiarity with the claimed invention and having reviewed the application and claims. In paragraph 5, Declarant asserts that he worked in a clinical trial of the claimed invention, the results of which indicated that the claimed invention “was generally a success and preferred by

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the subjects of the trial”. At paragraph 6, Declarant asserts a familiarity with the reference to Rosenberg applied to the claims. At paragraph 7 Declarant states that he has compared the technology described in the claimed invention to that of Rosenberg, noting that Rosenberg describes a treatment for pilonidal cysts, as opposed to hemorrhoids, noting that Rosenberg teaches strapping the patient’s buttocks with adhesive strapping crossing in the front of the abdomen. Continuing, Declarant asserts that “a marked difference between Rosenberg and the claimed invention is that the strapping of Rosenberg operates by pulling on tissue to change the anatomic nature of the presacral skin and subcutaneous tissue of the buttocks to eliminate the natal cleft” Continuing, Declarant asserts that the structure of the instant invention allows it to operate in a different manner by distracting the buttocks to keep the skin in the perianal area from rubbing the inflamed tissue”. At paragraph 8, Declarant states that the differences between the invention and the prior art “show the superiority of the claimed invention” since the claimed invention can provide enhanced hemorrhoidal healing. At paragraph 9, Declarant states that in his opinion, the superiority of the instant device, and the differences between the instant device and the prior art would not have been obvious to one of ordinary skill in the art at the time the application was filed, and that Rosenberg does not show the claimed invention.

The examiner notes the statements made by Declarant in paragraphs 1-6. Subsequent statements, however, require closer scrutiny. Declarant’s statement in paragraph 7, that the device of Rosenberg “operates to change the anatomic nature of the presacral skin and subcutaneous nature of the buttocks to eliminate the natal cleft.” It is noted, however, as the natal cleft is “The groove or crack between the buttocks that runs from below the sacrum to the perineum; or the groove in which the anus is situated” (from <http://www.biology-online.org>), it is

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clear that the instant device and that of Rosenberg are both intended to operate on the same bodily structure. Further, given that each device operates to pull the buttocks apart (to change the anatomic nature of the buttocks, and the subcutaneous tissue thereof), so as to increase the angle of the cleft and that this is done to reduce or eliminate “all factors causing friction” (see Rosenberg, page 290, column 1, second paragraph, second sentence), it is unclear what, if any “marked difference” there is between the operation of the two devices. Thus while the assertion of superiority in paragraph 8 is noted, it remains only an assertion. Declarant’s opinion that the differences between the two devices would not be obvious, asserted in paragraph 9 are also noted. However, the legal test for obviousness is not whether the differences between two devices are obvious, but rather whether one of ordinary skill in the art would find it obvious to modify the prior art device to produce the claimed device, given the teachings of the prior art and the knowledge and level of skill of one of ordinary skill in the art. Thus while Declarant may find that “Rosenberg does not show the claimed invention”, the examiner notes that both devices seek to prevent mechanical friction on tissue which is healing; both devices do so by allowing the buttocks to be held separated, so as to minimize such friction; both devices effect this separation by employing adhesive elements that maintain the buttocks in a separated condition, while allowing the wearer to proceed with normal activities, and thus the devices are quite similar in their structure and operation.

With regard to the election by original presentation, applicant asserts that the examiner has failed to provide “reasonable examples that recite material differences” to show that claims 28-32 are distinct. In order to make the record more complete, the examiner presents herein an explanation of the material differences between the apparatus and method of use. The details of

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the application of the device to the body recited in the apparatus claims merely constitute statements of intended use, and do not add anything to the structure of the device already recited. As such, the device could be employed in a rolled up configuration and inserted into the gluetial cleft of the user above and below the hemorrhoidal tissue, the adhesive serving to secure the rolled up device in the rolled up configuration and/or to secure the device to the user's tissue. Therefore the method of use of the device recited in claims 28-32 is distinct from the claimed apparatus, and the restriction is proper.

The examiner has reviewed applicant's remarks regarding the holding of new matter in the previous office action. It is clear from the originally filed disclosure that the rubber separation knobs were disclosed in the text of the originally filed disclosure, thus this objection, with respect to the specification, has been withdrawn.

With regard to the rejection under 35 U.S.C. 112, second paragraph, applicant's amendments have obviated this rejection.

Regarding the prior art, applicant first addresses the Rosenberg publication, noting that there is no disclosure in Rosenberg that the device disclosed therein is "crescent shaped" as now claimed. However, the examiner notes that this shape is not critical, as set forth at page 13, lines 27-29 "Tape 30 may be made in any shape, such as the crescent-like shape shown in Figure 3, or other suitable shapes." And while Rosenberg does not show a crescent shape, this does not eliminate Rosenberg as a reference under 35 U.S.C. 103(a). Pointing to the Declarations filed under 37 C.F.R. 1.132, applicant asserts that the instant device can provide a wide range of benefits for the user, as denoted in the Declarations, and the differences between the instant device and that of Rosenberg.

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As set forth above, the assertions of many benefits and differences in the structure and method of application of the instant device and that of Rosenberg are noted, however, it is unclear to the examiner why any modification of Rosenberg to allow it to act on hemorrhoidal tissue would be unobvious to one of ordinary skill in the art. To summarize, as the instant invention is directed to the treatment of hemorrhoids, one of ordinary skill in the art is one who would normally treat hemorrhoids, e.g. a proctologist or other surgeon. Given that, the training for one of ordinary skill in the art would require not only 12 years of primary and secondary school, but 4 years of college, 4 more years of medical school, and additional years as an intern before qualifying as a proctologist or other surgeon. Given this high level of skill, the proposition that one of ordinary skill in the art would not realize that a treatment for the wound generated by the treatment for pilonidal cysts, wherein the buttocks are separated from the wound and maintained in this position by adhesive means, and wherein the reason for this is that healing is prevented by “all factors causing friction in daily work habits prevented epithelialization” (see Rosenberg, page 290, column 1, second paragraph, third sentence), as referenced above, it strains the bounds of credulity to assert that an individual with such a high level of skill would be unable to envision the use of a device as taught by Rosenberg to treat hemorrhoids – a condition which has long been recognized as exacerbated by friction (see the supplied references to Tallent {specifically see column 2, lines 37-40} and McFaul, Sr. {specifically see column 1, lines 7-10}) and wherein the friction arises, at least in part, from the very bodily structure as in the case of pilonidal cysts, i.e. the buttocks. And it is similarly difficult to imagine that such a skilled practitioner would be unable to modify the device of Rosenberg to provide the desired effects of separation of the gluetial cleft such that the

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hemorrhoids are not interfered with, especially in view of the fact that the originally filed disclosure specifically states that the device can be configured as a single strip which stretches from hip to hip, across the buttocks, as set forth at page 15, lines 14-19: “the strip may be a single strip that is intended to stretch from one hip, across the buttocks to the other hip (in which case each buttock would be attached), or a single strip that attaches to each buttock and wraps around the front of the affected individual.”

Continuing, applicant argues that (as set forth in the Declarations) that due to “the unique shape and structure, inflamed tissue caused by a hemorrhoid can be lifted at a specific angle that follows the anatomy of the patient’s body”. This argument is interesting, in that there is no mention whatsoever in the originally filed disclosure of lifting tissue “at a specific angle”. As this is nowhere discussed in the originally filed disclosure, this must be knowledge which is within the scope of one of ordinary skill in the art. As such, the knowledge of the desire to so lift the tissue, as well as the “specific angle” which is required would have been obvious to one of ordinary skill in the art.

The remainder of applicant’s arguments consist of reiterating the points made in the Declarations, and as such have already been addressed above with respect thereto. Therefore, the examiner will not burden the record by repeating them here, instead applicant is referred to these arguments as enumerated above.

The rejections based on DeMarco, Diaz, and Valentin have been withdrawn. It is noted that applicant’s supposition that the Valentin reference was intended to be applied under 35 U.S.C. 102(e), rather than 35 U.S.C. 102(c) is correct.

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The amendment filed November 12, 2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the number, location, and size of the rubber separation knobs, as well as the relative location of the knobs with respect to each other in the newly submitted Figure, and that the length is at least twice or at least three times the width.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-15, 19, 21, 27, 33-36, and 38-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosure is silent on the length is at least twice or at least three times the width.

Claims 13-15, 19, 21, 27, 33-36, and 38-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg. Rosenberg teaches a device such as claimed except for the crescent shape and the rubber separation knobs. It would have been obvious to the artisan of ordinary skill to configure the device of Rosenberg in a crescent shape, since this is not critical; is well within the scope of one having ordinary skill in the art; provides no unexpected result;

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and would allow the device to more closely conform to the body of the user, and to lift the tissue at a particular angle, which is within the knowledge of one of ordinary skill in the art, as set forth above, and to employ rubber separation knobs on the devices of Rosenberg, since such knobs are known to provide better frictional engagement with compliant surfaces to which they are applied, thus producing a device such as claimed.

Applicant's arguments filed November 12, 2009 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson, can be reached on Monday through Friday from 7:00 a.m. to 3:30

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p.m. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/david shay/

Primary Examiner, Art Unit 3769